

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

DIANA STANLEY, On Behalf of Herself,
All Others Similarly Situated and the General
Public,

Plaintiff,

vs.

BAYER HEALTHCARE LLC,

Defendant.

CASE NO. 11cv862-IEG(BLM)

Order Granting Defendant's Motion
for Summary Judgment [Doc. 76];
Denying as Moot Plaintiff's Motion for
Class Certification [Doc. 57 & 68] and
Defendant's Motion to Exclude Expert
Testimony [Doc. 75]

Presently before the Court are Plaintiff's motion for class certification, Defendant's motion to exclude certain expert testimony, and Defendant's motion for summary judgment. All matters were fully briefed, and the Court heard oral argument. Upon review, for the reasons explained herein, the Court GRANTS Defendant's motion for summary judgment, and DENIES AS MOOT Plaintiff's motion for class certification and Defendant's motion to exclude expert testimony.

Factual Background

Plaintiff Diana Stanley brings this action against Defendant Bayer Healthcare LLC on behalf of herself and others similarly situated alleging violation of the Consumer Legal Remedies Act (Cal. Civ. Code § 1750 *et seq.*) (CLRA), Unfair Competition Law (Cal. Bus. & Prof. Code § 17200 *et seq.*) (UCL), breach of express warranty, and money had and received/unjust enrichment. [Complaint, Doc. No. 1.] Plaintiff invokes the Court's jurisdiction under the Class Action Fairness Act (28 U.S.C. § 1332(d)(2)) (CAFA). [Complaint, ¶ 1.] The Complaint states

claims based upon Defendant's sale of three particular products: Phillips' Colon Health Probiotic Supplement, Phillips' Colon Health Probiotic Caps, and Phillips' Colon Health Probiotic + Fiber (collectively the "Products" or "PCH"). [Complaint, ¶¶ 24-26.]

1. Plaintiff's purchase and use of PCH

After her doctor recommended she take probiotics¹ to relieve diarrhea she had been experiencing, Plaintiff purchased one 30-Count bottle of Phillips' Colon Health Probiotic Caps on April 7, 2011. [Complaint, ¶ 3; Deposition of Diana Stanley ("Stanley Depo."), Exhibit 2 to the Declaration of Skye Resendes in Opposition to Defendant's MSJ ("Resendes Decl."), at 83:17-25, 194:19-21.] The pharmacist recommended PCH, and Plaintiff also read the outside of the box to see what symptoms PCH could relieve. [*Id.*, at 88:12 - 89:5.] The one statement on the PCH package on which Plaintiff relied for her purchase stated: "Helps Defend against Occasional DIARRHEA." [Declaration of Kara McCall in Support of Defendant's MSJ ("McCall Decl."), Exhibit D, p. 23 (copy of box of 30-Count PCH Probiotic Caps); Stanley Depo., at 89:6-15.] Prior to purchasing PCH, Plaintiff never saw any advertisements for the product. [Stanley Depo., at 93-94.] Plaintiff used PCH for approximately six or seven days. [Deposition of Diana Stanley, Exhibit E in Support of Defendant's MSJ, at 98:3-5.] She stopped taking PCH after that time because she was not getting any relief for her diarrhea. [Stanley Depo., at 102:21-24.] Plaintiff filed the class action complaint in this case just over a week later, on April 22, 2011.

2. Other representations regarding effectiveness of PCH

Although Plaintiff purchased only the 30-Count box of Phillips' Colon Health Probiotic Caps, the Complaint states claims based upon Defendant's sale of other size boxes of the Probiotic Caps as well as two additional products: Phillips' Colon Health Probiotic Supplement and Phillips' Colon Health Probiotic + Fiber (collectively the "Products" or "PCH"). [Complaint, ¶¶ 24-26.] All of the Products are prominently labeled with several claims relating to the PCH's benefits to digestive and immune health including the following:

¹According to the National Center for Complementary and Alternative Medicine, probiotics "are live microorganisms (in most cases, bacteria) that are similar to beneficial microorganisms found in the human gut. They are also called 'friendly bacteria' or 'good bacteria.' Probiotics are available to consumers mainly in the form of dietary supplements and foods." www.nccam.nih.gov/health/probiotics (visited 3/7/12).

- replenishes GOOD BACTERIA to promote overall DIGESTIVE HEALTH
- helps NATURALLY PROMOTE REGULARITY
- supports a HEALTHY IMMUNE SYSTEM

[Complaint, ¶ 27; McCall Decl., Exhibit D (copies of packaging and labels for the Products).]

3. Plaintiff's legal claims

Plaintiff alleges Defendant's statements regarding PCH are false and mislead the public into the belief that consumption of PCH, on a consistent and regular basis, will improve digestive and immune health. [Complaint, ¶ 37.] Plaintiff alleges "[d]espite a complete lack of scientific or clinical data to support its claims, Bayer disregards accurate advertising in the interest of maximizing profits and charging consumers a premium for its health supplement products." [Id.] Plaintiff alleges Defendant "deceptively conveys the marketing message that the Products deliver unique benefits however fails to provide the consumer with a single bit of information that would support its claims." [Complaint, ¶ 43.] Plaintiff alleges Defendant's claims about the benefits of the Products "are not substantiated by the vast majority of generally accepted scientific literature currently available relating to probiotics." [Complaint, ¶ 50.] Plaintiff alleges Defendant's advertising "overwhelmingly conveys to the consumer that its Products will improve one's digestive health and immune system function, purportedly based on sound scientific principles and the positive benefits of probiotics." [Complaint, ¶ 44.]

Plaintiff alleges defendant's advertisements and representations are unsubstantiated, false, and misleading in violation of the CLRA. [Complaint, ¶ 65.] Plaintiff also asserts Defendant "engaged in unfair, deceptive, untrue and misleading advertising" by "making the representations and omissions of material facts" in violation of the UCL. [Complaint, ¶¶ 70-71.] Finally, Plaintiff asserts a claim for breach of contract, alleging that Defendant's product labeling and advertising "constitutes express warranties, became part of the basis of the bargain, and is part of a standardized contract between plaintiff ... on the one hand, and Bayer on the other." [Complaint, ¶ 83-85.]

Legal Standard

Summary judgment is proper where the pleadings and materials demonstrate “there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c)(2); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). A material issue of fact is a question a trier of fact must answer to determine the rights of the parties under the applicable substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Id. The court must review the record as a whole and draw all reasonable inferences in favor of the non-moving party. Hernandez v. Spacelabs Med. Inc., 343 F.3d 1107, 1112 (9th Cir. 2003). However, unsupported conjecture or conclusory statements are insufficient to defeat summary judgment. Id.; Surrell v. Cal. Water Serv. Co., 518 F.3d 1097, 1103 (9th Cir. 2008).

A non-moving party who bears the burden of proving at trial an element essential to its case must sufficiently establish a genuine dispute of fact with respect to that element or face summary judgment. See Celotex Corp., 477 U.S. at 322–23. Such an issue of fact is a genuine and material issue if it cannot be reasonably resolved in favor of either party and may affect the outcome of the suit. See Anderson, 477 U.S. at 248, 250–51.

Discussion

Defendant seeks summary judgment arguing lack of substantiation is not a basis for relief under the UCL or CLRA and Plaintiff has failed to show any of the statements made regarding the Products are false or misleading. Defendant also argues it is entitled to summary judgment on Plaintiff’s claim for unjust enrichment because there is no such stand-alone cause of action under California law.

a. Legal Elements of Claim for false advertising under UCL and CLRA

California’s UCL prohibits any “unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising” Cal. Bus. & Prof. Code § 17200 and 17500. California’s CLRA generally prohibits “unfair methods of competition and unfair or deceptive acts or practices” Cal. Civ. Code § 1770. In evaluating a claim under the UCL and CLRA, courts are guided “by the ‘reasonable consumer’ test.” Williams v. Gerber Products Co.,

1 552 F.3d 934, 938 (9th Cir. 2008) (quoting Freeman v. Time, Inc., 68 F.3d 285, 289 (9th Cir.
 2 1995)). Under such standard, Plaintiffs “must ‘show that members of the public are likely to be
 3 deceived’.” Williams, 552 F.3d at 938 (quoting Bank of West v. Superior Court, 2 Cal. 4th 1254,
 4 1267 (1992)). The UCL and CLRA prohibit “not only advertising which is false, but also
 5 advertising which although true, is either actually misleading or which has the capacity, likelihood
 6 or tendency to deceive or confuse the public.” Kasky v. Nike, Inc., 27 Cal. 4th 939, 951 (2002).

7 In an action for false advertising under the UCL and CLRA, the plaintiff “bears the burden
 8 of proving the defendant’s advertising claim is false or misleading.” National Council Against
 9 Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc., 107 Cal. App. 4th 1336, 1342 (2003). Private
 10 individuals may not bring an action demanding substantiation for advertising claims. Instead,
 11 pursuant to Cal. Bus. & Prof. Code § 17508, only prosecuting authorities may require an advertiser
 12 to substantiate its advertising claims. Id. at 1343; see also Chavez v. Nestle USA, Inc., 2011 WL
 13 2150128, *5-6 (C.D. Cal. May 19, 2011) (dismissing plaintiff’s claim for false advertising because
 14 plaintiff’s factual allegation that defendant did not possess requisite scientific evidence for claims
 15 was insufficient to state a claim under California false advertising law); Fraker v. Bayer Corp.,
 16 2009 WL 5865687, *8-9 (C.D. Cal. Oct. 6, 2009) (dismissing plaintiff’s claim for false advertising
 17 because plaintiff alleged only that defendant had “no reasonable basis, consisting of competent and
 18 reliable scientific evidence to substantiate” its health-benefit claim related to “WeightSmart”
 19 multivitamin). The purpose of allowing only prosecuting authorities, and not private persons, to
 20 seek substantiation of advertising claims under Cal. Bus. & Prof. Code § 17508 is to “prevent
 21 undue harassment of advertisers” and provide “the least burdensome method of obtaining
 22 substantiation for advertising claims.”

23 A plaintiff may state a claim under the CLRA or UCL based upon alleged omissions of fact
 24 in advertising. However, such plaintiff must first demonstrate the defendant had a duty to
 25 disclose. Chavez, 2011 WL 2150128, at *6-7. This duty may arise in four circumstances: “(1)
 26 when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had
 27 exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively
 28 conceals a material fact from the plaintiff; and (4) when the defendant makes partial

representations but also suppresses some material fact.” Wilson v. Hewlett-Packard Co., __ F.3d __, 2012 WL 502442, at *5 (9th Cir. Feb. 16, 2012). A “material fact” is shown where “had the omitted information been disclosed, one would have been aware of it and behaved differently.” Id. The standard for “deceptive practices” under the “fraudulent” prong of the UCL applies equally to misrepresentation-based claims under the CLRA, such that it is appropriate to analyze such claims together. O’Shea v. Epson America, Inc., 2011 WL 3299936 (C. D. Cal. July 29, 2011) (citing Paduano v. American Honda Motor Co., Inc., 169 Cal. App. 4th 1453, 1468-69 (2009)).

b. Plaintiff’s False Advertising Claims regarding PCH

Defendant moves for summary judgment, arguing that Plaintiff has not offered any evidence supporting her claim that Defendant’s advertising and packaging of the Products is deceptive, untrue, or misleading. Instead, Defendant argues, Plaintiff’s complaint is based entirely upon an alleged failure to substantiate, which is not actionable. In opposition, Plaintiff argues (i) Defendant’s advertising is actually false and misleading because there is insufficient scientific evidence to support the general claim that PCH promotes overall digestive health and helps defend against occasional diarrhea and other gastrointestinal problems, and (ii) Defendant’s advertising is false and misleading because Defendant never conducted strain specific studies of the 3 strains of probiotics in combination as represented on its packaging and advertising .

i. Sufficiency of Scientific Evidence to Support General Claims

Review of the summary judgment motion, as well as Plaintiff’s motion for class certification, has been difficult because even though Plaintiff acknowledges she cannot pursue a claim based upon lack of substantiation of Defendant’s health claims regarding PCH, the vast majority of Plaintiff’s pleadings and filings are targeted at this argument. In fact, Plaintiff’s motion for class certification, which she filed before Defendant filed its motion for summary judgment, focuses almost entirely upon the alleged lack of scientific substantiation for the proposition that the probiotics in PCH improve digestive and immune system health. Plaintiff argues *at length* both in her motion for class certification and in opposition to the summary judgment motion that Defendant’s claims regarding the general digestive and immune system health benefits of PCH are actually false because they lack proper scientific substantiation.

1 However, the alleged lack of substantiation does not render claims false and misleading under the
2 UCL or CLRA.

3 Defendant makes the following general representations on the outside of the PCH Probiotic
4 Caps 30-count box which Plaintiff purchased²:

- 5 • “3 strains of good bacteria to promote overall digestive health”
- 6 • “Helps Defend Against Occasional constipation, diarrhea, gas and bloating”
- 7 • “This once-daily capsule contains probiotics to help with occasional constipation,
8 diarrhea, gas and bloating”
- 9 • “Contains the most common and most studied bacteria for digestive health
(*Lactobacillus* and *Bifidobacterium* which closely resemble your body’s natural
good bacteria”
- There’s scientific evidence that *Lactobacillus* and *Bifidobacterium* help relieve gas,
diarrhea, constipation and other GI discomforts

10 [McCall Decl., Exhibit D, p. 23.] The outside of the boxes of the PCH Probiotic Caps 45-count
11 product, and PCH Probiotic + Fiber product, contain similar general representations regarding the
12 health benefits of the products.

13 Plaintiff argues these general claims are false and misleading because “a majority of data
14 generated in peer reviewed, double blind, placebo controlled studies, relating to probiotics, largely
15 suggests that probiotics have little effect on human digestive or immune health.” [Declaration of
16 Patrick Gillevet, Ph.D., in Support of Plaintiff’s Motion for Class Certification (“Gillevet Decl.”),
17 ¶ 18.] Dr. Gillevet opines that “[Defendant’s] health claims concerning its Products can and
18 should be evaluated using the current scientific methods and established protocols such as
19 Metagenomics, Metabiomics, and Transcriptomics and the use of appropriate controls.” [Gillevet
20 Decl., ¶ 14³.] Dr. Gillevet also opines that “proving the efficacy and safety of substances used to
21 treat disease and improve health also requires correctly designed randomized, controlled clinical
22 trials.” [Id. at ¶ 16.] Because Defendant did not independently conduct these types of clinical
23 studies of its PCH products, Plaintiff argues the general health representations that PCH “promotes
24

25 ²Plaintiff did not keep the actual box she purchased. However, both parties have provided
26 copies of the box and bottle labels for the 30-count box and there is no dispute that those copies
accurately reflect the box Plaintiff purchased.

27 ³Dr. Gillevet’s declaration contains no definition of the terms Metagenomics, Metabiomics,
28 or Transcriptomics. According to the National Institutes of Health, Metagenomics is the study of a
collection of genetic material (genomes) from a mixed community of organisms. I could not find a
definition of Metabiomics or Transcriptomics from a trusted internet source.

1 overall digestive health” and “helps defend against occasional constipation, diarrhea, gas and
2 bloating” are rendered false and misleading for lack of substantiation.⁴

3 However, none of Plaintiff’s experts opine that the claims PCH “Helps Defend Against
4 Occasional constipation, diarrhea, gas and bloating” or “promotes overall digestive health” are
5 actually false, or explain how those statements might mislead a reasonable consumer. Instead,
6 Plaintiff’s experts repeatedly assert the statements are rendered false or misleading due to a lack of
7 substantiation. At his deposition, Dr. Gillevet testified that probiotics may provide benefits to
8 some people:

9 Q: You state [in your expert report] that “It has been established that the
10 response of individuals to prebiotics and probiotics *varies dramatically* between
11 individuals.” What is the basis for that opinion?

12 A. If you just look at the publications and look at how broad the effects are, if
13 you look at the standard deviations, they’re huge, all right? Transit time, okay, 12
14 hours, plus or minus 20 hours, I mean, what does that mean? There’s huge
15 variation.

16 Q. So in essence are you saying here, then, that probiotics provide health
17 benefits to some people and probiotics provide – don’t provide health benefits to
18 others?

19 A. You can’t say, because of the variation. There’s no – you can’t scientifically
20 conclude anything.

21 Q. Okay. So you can’t rule out that probiotics do work for some people?

22 A. It’s inconclusive.

23 [Gillevet Depo., McCall Decl., Exhibit C, 113:16 - 114:91 .] At no time does Dr. Gillevet opine
24 that probiotics, or PCH in particular, are ineffective to help defend against occasional constipation,
25 diarrhea, gas and bloating. There is no evidence that Dr. Gillevet himself has conducted research
26 regarding the effectiveness of PCH. In fact, at the time the Plaintiff’s experts gave their
27 depositions and rendered their reports, they had not reviewed any of the 161 articles Defendant
28 produced regarding the usefulness of the probiotics contained in PCH in supporting immune
system and general digestive health. [Gillevet Depo., 184-85; Rose Depo., 147, 165.]

Plaintiff’s expert Dr. Rose also opines that Defendant’s claim regarding PCH are not
substantiated. [Deposition of Noel R. Rose, M.D., McCall Decl., Exhibit B, at 12:2-5; Declaration

⁴It is undisputed that Defendant did not independently conduct clinical studies of the
combination of the 3 strains of probiotics contained in each of the PCH products. [Deposition of
Gary Huffnagle, Exhibit 24 to Plaintiff’s Motion for Class Cert., 133:3-16, 136:4-139:4, 163:5-
166:8, and 201:16-22 (confirming that Defendant did not independently conduct clinical studies of
the 3 strains of probiotics in PCH but instead relied on a study by Wakunaga of America as well as
other studies in the public domain).]

1 of Noel R. Rose, M.D., McCall Decl. Exhibit H, ¶¶ 8-11.] Dr. Rose testified that “taking a
 2 probiotic can be beneficial for some people but may be harmful for others ... [T]hey may be of
 3 benefit to the same individual at some point in time and may be detrimental at other points in time.
 4 So it’s not just different people, but the same person under different conditions, at a different age,
 5 under a different circumstance.” [Rose Depo., at 105:6-18.] Dr. Rose acknowledged that PCH
 6 could be beneficial to a lot of users. [*Id.*, at 144:11-19.]

7 Plaintiff argues that because there are no studies of the Proprietary Blend in PCH, there is a
 8 genuine issue of material fact as to whether Defendant had any substantiation for PCH as required
 9 by the Food, Drug, and Cosmetics Act (“FDCA”), 21 U.S.C. § 343(r)(6)(A).⁵ Plaintiff lists several
 10 “facts” in its Separate Statement based upon the argument the FDCA requires Defendant to have
 11 “scientific substantiation” for its PCH products and the only way to satisfy that standard is to
 12 conduct strain-specific human studies. [Plaintiff’s Separate Statement, ¶¶ 34-43.] However, a
 13 Plaintiff may not pursue a claim under the UCL or CLRA based upon lack of substantiation.
 14 Chavez, 2011 WL 2150128, at *5-6; National Council Against Health Fraud, Inc., 107 Cal. App.
 15 4th at 1343.

16 At the time of the hearing, Plaintiff argued for the first time that she could assert a claim of
 17 lack of substantiation under the “unlawful conduct” prong of the UCL. Plaintiff argued she could
 18 proceed with a claim against Defendant under the UCL if Defendant failed to properly substantiate
 19 its claims pursuant to the standards set by the FDCA. This claim was not included in Plaintiff’s
 20 complaint, and was not briefed by Plaintiff in opposition to summary judgment. In fact, had such
 21 claim been raised, the Court likely would have required additional briefing as to the issue of
 22 preemption. See Degelmann v. Advanced Medical Optics, Inc., 659 F.3d 835, 840-41 (9th Cir.
 23 2011) (where plaintiff asserted UCL and false advertising claims based upon defendant’s alleged
 24 failure to meet federal labeling standards, court was required to undertake analysis as to whether
 25 such claim was preempted.) Furthermore, Plaintiff’s argument that she can assert a UCL

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 27 ⁵Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6)(B), “a statement
 28 for a dietary supplement may be made if ... the manufacturer of the dietary supplement has
 substantiation that such statement is truthful and not misleading” The federal and state
 government both have mechanisms for requiring manufacturers to substantiate statements
 regarding the dietary supplements.

1 “unlawful conduct” claim based upon violation of the FDCA is precluded by the California Court
 2 of Appeal’s opinion in King Bio Pharmaceuticals, 107 Cal. App. 4th at 1344 (“[p]rosecuting
 3 authorities, but not private plaintiffs, have the administrative power to request advertisers to
 4 substantiate advertising claims before bringing actions for false advertisement”).

5 Even if Plaintiff could pursue such a claim, Plaintiff has failed to demonstrate a genuine
 6 issue of material fact regarding whether Defendant complied with federal regulatory standards for
 7 substantiation. Defendant’s regulatory expert, Dr. Elizabeth Campbell, opines that PCH is not a
 8 drug or a biologic. It is a dietary supplement. [Report of Elizabeth Campbell (“Campbell Rep.”),
 9 Exhibit G to Declaration of Kara McCall in Support of Motion to Exclude (“McCall Exclude
 10 Decl.”), p. 7] Within the FDA regulatory scheme, dietary or nutritional supplements are
 11 considered in a category separate and apart from drugs. [Campbell Rep., pp. 2-3.] Manufacturers
 12 of dietary supplements are permitted by the FDA to make several different types of claims about
 13 the health benefits of their products in labels, such as health claims, nutrient content claims, and
 14 structure/function claims. [Campbell Rep., p. 3.]

15 Under the Dietary Supplement Health and Education Act of 1994 (“DSHEA”), certain
 16 types of claims about the uses of dietary supplements are specifically authorized. In particular, the
 17 DSHEA allows dietary supplement labeling to bear, among other types of statements, a statement
 18 that “describes the role of a nutrient or dietary ingredient intended to affect the structure or
 19 function in humans” or that “characterizes the documented mechanism by which a nutrient or
 20 dietary ingredient acts to maintain such structure or function.” These structure/ function claims
 21 are not required to be pre-approved by the FDA. Instead, companies that intend to make such
 22 claims must provide notice to the FDA within 30 days of first use of the claim, and must include a
 23 disclaimer on the label stating that the FDA has not evaluated the claim and that the product is not
 24 intended to “diagnose, treat, cure or prevent any disease.” [Campbell Rep., pp. 3-4 (citing 21
 25 U.S.C. § 343(r)(6)(C); 21 C.F.R. § 101.93).]

26 Dr. Campbell opines that the following statements regarding PCH are all “structure/
 27 function claims”: PCH contains “3 strains of good bacteria to promote overall digestive health,”
 28 can “help support immune system,” and “helps defend against occasional constipation, diarrhea,

1 gas, and bloating.” [Campbell Rep., p. 6.] Defendant submitted these structure/function claims to
2 the FDA as required, and the FDA did not object to them or otherwise challenge the product.
3 [McCall Exclude Decl., Exhibit J (Defendant’s 30-Day notice with regard to structure/function
4 claims of the PCH Products).]

5 In an attempt to rebut Defendant’s argument, Plaintiff presents opinions from Dr. Gillevet
6 that Defendant is making “health claims” as that term is defined by the FDA, and that Defendant
7 was required to substantiate its claims related to PCH through more thorough, peer-reviewed,
8 conclusive, rigorous, testing. [Gillevet Depo., at 10, 14-15, 56-57, 59-60, 90, 120, 126, 159, and
9 160; Gillevet Report, ¶¶ 1, 16, 18, 19, 21, 30, 51 (referring to Defendant’s claims as “health
10 claims”).] However, Dr. Gillevet admitted in his deposition that he has no regulatory expertise
11 whatsoever, and he has no idea how the FDA defines “health claim.” [Gillevet Depo., at 15, 56-
12 57, 74.] Similarly, Dr. Rose opined that he believes Defendant should have the same support for
13 its PCH claims as drug companies must have for their drug claims, i.e. proof of efficacy in
14 placebo-controlled double-blind human studies. [*Id.*, 143:14-144:22, 176:8-177-14.] Nonetheless,
15 Dr. Rose testified he does not know anything about how the FDA defines “health claims” or
16 “structure/function claims.” [Rose Depo., at 22:4-12.] Plaintiff cannot create a genuine issue of
17 material fact regarding whether Defendant met the level of substantiation required under federal
18 law by presenting opinions from experts who are not aware of the relevant regulatory standards.

19 Plaintiff argues her claims under the UCL and CLRA are supported by the fact PCH did
20 not work for her. In particular, Plaintiff read the statement on the PCH Probiotic Caps package
21 that it “helps defend against occasional diarrhea” as promising “you would have a better digestive
22 system, your immune system would be improved, and it would stop occasional gas and diarrhea.
23 [Stanley Depo., 22:13-22, 140:6-13, 140:22-24.] Plaintiff believed PCH was “a medication [of]
24 sorts” and it was her impression from reading the outside of the PCH box that the product was
25 intended to “relieve [] diarrhea.” [*Id.*, 134:24 - 135:3, 89:6-15.] However, as required by 21 U.S.C.
26 § 343(r)(6)(C), the side panel of the PCH box stated “[t]his product is not intended to diagnose,
27 treat, cure, or prevent any disease.” [McCall Decl., Exhibit D, p. 23.] Furthermore, at the time
28 Plaintiff purchased PCH, she suffered from a condition known as diverticulitis which was treated

1 with antibiotics.⁶ [Stanley Depo., 80, 83, 194, 222, 222-25, 231.] Plaintiff's doctor recommended
 2 she take probiotics to help with the diarrhea, but did not recommend PCH in particular. [*Id.*, at
 3 222:6-19.] Plaintiff's experts did not provide an opinion regarding why PCH did not work to
 4 relieve Plaintiff's particular diarrhea symptoms. As Defendant points out, nothing on the PCH
 5 box, internal packaging, or advertisement represents to consumers that the product is intended to
 6 relieve diarrhea. The fact PCH did not relieve Plaintiff's diarrhea does not mean a reasonable
 7 consumer would be mislead into believing it would work as Plaintiff suggests. The Plaintiff has
 8 failed to produce any evidence that the product does not work for the purposes for which it is
 9 advertised – to promote overall digestive health and to defend against occasional diarrhea and
 10 other gastrointestinal issues.

11 Persuasive with regard to this argument is a decision by the Los Angeles County Superior
 12 Court, granting summary judgment on a similar UCL false advertising claim. Fletcher v. Celsius
 13 Holdings, Inc., Case No. BC439 055 (Sept. 1, 2011) [Second Declaration of Kara McCall in
 14 Support of Defendant's MSJ Reply ("McCall 2d Decl."), Exhibit J.] In Fletcher, the court
 15 evaluated plaintiff's claim under the UCL that defendant's product failed to burn up to 100
 16 calories per can, resulting in weight loss. Plaintiff purchased a product which promised, on its
 17 label, that consumption of the product results in burning up to 100 calories per can. [*Id.*, p. 9.]
 18 Plaintiff read the product label as promising weight loss, and brought suit for false advertising
 19 under the UCL when he did not, in fact, lose weight. The court found plaintiff's claim to be
 20 without merit as a matter of law, because plaintiff's belief that the label promised weight loss
 21 reached beyond what a reasonable consumer could have justifiably relied. [*Id.*, p. 11.]
 22 Furthermore, the court noted there was no evidence to show why the product did not result in
 23 weight loss for the plaintiff. Plaintiff varied his consumption of the product as well as his food

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 25 ⁶According to the Mayo Clinic online, diverticulitis "occurs when one or more diverticula
 26 in your digestive tract become inflamed or infected. Diverticula are small, bulging pouches that
 27 can form anywhere in your digestive system, including your esophagus, stomach and small
 28 intestine. However, they're most commonly found in the large intestine. Diverticula are common,
 especially after age 40. When you have diverticula, the condition is known as diverticulosis. You
 may never even know you have these pouches because they seldom cause any problems, such as
 diverticulitis. Sometimes, however, diverticulitis occurs. This condition can cause severe
 abdominal pain, fever, nausea and a marked change in your bowel habits."
 mayoclinic.com/health/diverticulitis/DS00070 (visited 3/6/12).

1 intake and exercise regimen; he never measured his metabolism or caloric consumption, and never
2 kept records of his weight. Thus, plaintiff had no evidence regarding why the product did not
3 work for him. As a result, the court found plaintiff could not demonstrate deception or falsity
4 resulting in his injury in fact. [*Id.*, pp. 17-18.]

5 Similarly, a reasonable consumer would not read the PCH package as promising to
6 “relieve” diarrhea. There are a whole host of products on the market to treat ongoing diarrhea.
7 PCH is not one of those products. PCH is a probiotic, the packaging and advertisement of which
8 indicate it is intended to promote overall digestive health and defend against occasional
9 gastrointestinal problems. Plaintiff has presented no evidence that these health-related claims of
10 the Products are false or misleading, and has presented no evidence attempting to explain why
11 PCH did not work for her. Liability for false advertising under the UCL and CLRA cannot be
12 based upon the fact that PCH did not work for Plaintiff in the way she believed (but Defendant did
13 not represent) it would. The burden is upon Plaintiff to present evidence that Defendant’s
14 advertising claims are actually false or misleading. Chavez, 2011 WL 2150128, at *5; National
15 Council Against Health Fraud, Inc., 107 Cal. App. 4th at 1343.

16 Finally, Plaintiff attempts to argue that Defendant’s advertising regarding PCH is deceptive
17 and misleading because Defendant omitted to disclose material facts to the consumers which
18 would influence their purchasing decision. Chavez, 2011 WL 2150128, at *6 (setting forth ways
19 to prove the fraud prong under California’s UCL based upon the omission or failure to disclose
20 facts). However, the only “fact” Plaintiff identifies that Defendant purportedly failed to disclose is
21 that, to be effective, PCH should be taken continuously for an unknown period of time. Although
22 the packaging of the PCH Probiotic Caps which Plaintiff purchased and used has changed over the
23 years, each package states on the front they are a “Daily Probiotic Supplement.” The back label
24 directs the tablets are to be taken “Daily” or “Everyday” to support digestive health. [McCall
25 Decl., Exhibit D, pp. 23-24, 32-44.] Plaintiff does not explain what additional “material fact”
26 Defendant had an affirmative duty to disclose. Wilson, 2012 WL 502442, at *5 (affirming district
27 court’s dismissal of claim of concealment of design defect where plaintiff failed to demonstrate
28 defendant’s knowledge of the alleged defect); Falk v. General Motors Corp., 496 F. Supp. 2d

1 1088, 1096-97 (N.D. Cal. 2007) (defendant had an obligation to disclose its knowledge of the
 2 defect in speedometers because it had exclusive knowledge and actually concealed such facts);
 3 Buller v. Sutter Health, 160 Cal. App. 4th 981, 988 (2008) (rejecting plaintiff's claim that
 4 hospital's failure to disclose the availability of a prompt-payment discount did not render such
 5 practice "unfair" under UCL where plaintiff demonstrated the hospital had an affirmative duty to
 6 disclose); Chavez, 2011 WL 2150128, at *6-7 (rejecting false advertising claim under theory of
 7 failure to disclose where plaintiff failed to establish defendant had a duty).

8 *ii. Defendant's particularized advertising claims*

9 In addition to arguing Defendant's general claims about PCH lack substantiation, Plaintiff
 10 argues Defendant's packaging and advertising contain an affirmative representation that Defendant
 11 conducted clinical studies of the combined effectiveness of the 3 probiotics contained in PCH.⁷
 12 Plaintiff cites a statement on the back of the packaging of the 45-count PCH Probiotic Caps, that
 13 the product "[c]ontains a proprietary blend of 3 clinically tested strains of good bacteria." [McCall
 14 Decl., Exh. D., p. 24.] Plaintiff, however, purchased the 30-count package, which did not contain
 15 the same language and there is no evidence Plaintiff read this statement on the 45-count package
 16 prior to making her purchase.⁸ [Id., p. 23.] Plaintiff does not recall reading or relying on any of the
 17 claims on the package other than the claim related to diarrhea contained on the front of the 30-
 18 count PCH Probiotic Caps box. [Stanley Depo., 89-90, 139-40.] Plaintiff also cites a statement
 19 Defendant made in letters it sent to doctors and pharmacists, that PCH contains "3 clinically tested
 20 strains of bacteria – more strains than other leading probiotic supplements." [Plaintiff's Opposition
 21 to MSJ, at 4:15-17 (citing Plaintiff's Mot. for Class Cert. 8:22-23, and 9:8-9; Declaration of
 22 Ronald Marron in Support of Plaintiff's Motion for Class Certification ("Marron Decl."), Exhibits

24 ⁷In her motion for class certification, Plaintiff states Defendant falsely represents "that
 25 PCH's proprietary blend of three different probiotics are superior to other forms available to the
 26 public. [Motion for Class Certification, p. 1, lines 17-18.] However, Plaintiff points to no language
 in Defendant's advertising or packaging asserting PCH's "superiority."

27 ⁸There is evidence in the record suggesting the 30-count and 45-count boxes of PCH
 28 Probiotic Caps would not have been located together. The 30-count box is sold in the digestive
 health section of retail stores while the 45-count product is sold with nutritional supplements.
 [Deposition of Laura Pinkett, Exhibit J to the Declaration of Kara McCall in Support of
 Defendant's Opposition to Motion for Class Certification ("McCall Cert. Decl."), at 73-74.]

15 and 16.] However, Defendant did not make these statements in advertising PCH to the public. There is no evidence Plaintiff, or the pharmacist who allegedly recommended PCH to Plaintiff, ever saw the letter.⁹ Thus, the statement cannot form the basis of Plaintiff's false advertising claim. Davis-Miller v. Automobile Club of So. Cal., 201 Cal. App. 4th 106, 124 (2011) (false advertising claim under UCL and CLRA require the class be exposed to the allegedly false advertising at issue); Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 327 (2011) (a plaintiff asserting a claim under the UCL and CLRA based upon false advertising must demonstrate actual injury by showing "the misrepresentation was an immediate cause of the injury-producing conduct....")

Plaintiff has failed to produce any evidence that she purchased PCH in reliance upon the statement on the 45-count box of PCH that the product "[c]ontains a proprietary blend of 3 clinically tested strains of good bacteria." Plaintiff has failed to show there is a genuine issue of material fact precluding entry of summary judgment in favor of Defendant on her false advertising claims under the UCL and CLRA.

c. Express Warranty Claim

Under California law a claim for breach of express warranty requires a showing of "the exact terms of the warranty, plaintiff's reasonable reliance thereon, and a breach of that warranty which proximately causes plaintiff injury." Williams v. Beechnut Nutrition Corp., 185 Cal. App. 3d 135, 142 (1986). Here, Plaintiff has failed to identify any "express warranty" made by Defendant regarding PCH. Nothing on the packaging warranted that use of the product for six or seven days would relieve Plaintiff's diarrhea. Plaintiff has also failed to present any evidence regarding why PCH did not help her gastrointestinal symptoms. Defendant is entitled to summary judgment on Plaintiff's express warranty claim.

d. Unjust Enrichment Claim

Finally, Plaintiff's independent claim for unjust enrichment is properly dismissed, regardless of whether the Court grants summary judgment on the UCL and CLRA claims. The

⁹Plaintiff testified that although her doctor recommended she take a probiotic, the doctor did not specifically recommend PCH. [Stanley Depo., 222:17-19.]


1 Complaint alleges Defendant received money and benefits as a result of its false and deceptive
 2 advertising, and thus was unjustly enriched. [Complaint, ¶¶ 88-91.] Unjust enrichment, however,
 3 “is a ‘general principle underlying various legal doctrines and remedies;’ it is not an independent
 4 cause of action.” Johns v. Bayer Corp., 2010 WL 476688, *6 (S.D. Cal. 2010) (DMS) (in case
 5 alleging claims under UCL and CLRA regarding defendant’s vitamin products, court dismissed
 6 claim for unjust enrichment concluding such claim fails as a matter of law); Walker v. USAA Cas.
 7 Ins. Co., 474 F. Supp. 2d 1168, 1174 (E. D. Cal. 2007) (where plaintiff brought claim under UCL
 8 as well as claim for unjust enrichment, court found “unjust enrichment is merely a synonym for the
 9 remedy of restitution and not a stand-alone cause of action.”). Therefore, the Court GRANTS
 10 summary judgment on Plaintiff’s separate claim for unjust enrichment.

11 Conclusion

12 For the reasons set forth herein, the Court GRANTS Defendant’s motion for summary
 13 judgment on Plaintiff’s claims, and DENIES AS MOOT Plaintiff’s motion for class certification
 14 and Defendant’s motion to exclude testimony.

15 **IT IS SO ORDERED.**

16 **DATED: April 3, 2012**

17 
 18 **IRMA E. GONZALEZ, Chief Judge**
 19 **United States District Court**